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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,912	01/07/2002	Denis Hunt	H0011/7000	4084

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01/18/2005

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EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,912

Applicant(s)

HUNT ET AL

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/15/2002 etc.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. The reference lined through on the IDS was not considered because the patent number did not correspond to the inventor name, and the patent number cited was irrelevant to the application.

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 31-34 have been renumbered 30-33. No claim 30 was presented.

3. Claims 17, 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. With respect to claim 17, no conical sleeve module is described in conjunction with a well plate. The conical sleeve module is described as used with a pipette tip. With respect to claim 34, there is no description of how to make or use the tool. While there are general statements that a tool can be provided to insert/remove the column module, there is no description of how to make the tool, or what structures on the tool are used with what structures on the module to insert/remove the module.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country; more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 1-5, 7, 10-11, 13, 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Horn (5918273).

Horn teaches a sample chamber 19 having a greater diameter than cylindrical column insert portion 35 joined by tapered portion 39. Column module 13 may be packed with a chromatography medium, such as derivatized silica having affinity for lipophilic proteins (col. 5, lines 1-15). See, e.g., Fig. 3F. With respect to claim 7, it is the examiner's position that the frit inherently acts to regulate flow. With respect to claim 10, see Fig. 11, where the upper portion of 130 is the sample chamber, the lower portion of 130 is the column insert, and fitting 131 is the removable top portion of module 13. With respect to claim 11, when a user uses a particular column, such as derivatized silica having affinity for lipophilic proteins, the user has inherently selected the packing. With respect to claims 13, 17, 18, see Figures 3A-3B and 4, col. 12, lines 55-60. The column insert has conical sleeve portions at the top and bottom.

9. Claims 6- 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horn as applied to claims above, and further in view of Shukla (6103195).

10. Horn fails to teach membranes to control flow.

11. Shukla teaches that membranes of different molecular weight cut offs (MWCO), such as UF membranes, can be used in addition to frits in columns to regulate flow rates and provide further separation (abstract, col. 3, lines 3-6, 25-35).

12. It would have been obvious to use the claimed membranes in addition to the frit of Horn in order to provide further separation and/or control flow as taught by Shukla. It

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would have been obvious to use a microporous membrane in order to vary the MWCO as taught by Shukla.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horn as applied to claims above, and further in view of Applicant's admitted prior art (AAPA).

Horn fails to teach stacked membranes.

AAPA teaches that stacked membranes are conventionally used in place of chromatographic packing (instant disclosure, page 4, lines 6-9).

It would have been obvious to provide stacked membranes in place of the packing of Horn in order to provide a known conventional alternative separation medium as taught by AAPA.

14. Claims 14-16, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horn as applied to claims above and further in view of Franciskovich (5603899).

The teachings of Horn are given above. Horn teaches that fluid can be drawn through the columns by vacuum (col. 9, line 5). Horn further teaches that the columns can be used for chromatography (col. 6, lines 10-23). Buffers can be provided (e.g., col. 11, lines 35-43).

Horn fails to teach a receiving plate with vessels, a barrier, the claimed buffers or different column contents.

Franciskovich teaches a system similar to that of Horn. The columns may have the same or different packings, including affinity packings (col. 4, lines 1-2, lines 53-59), and the columns may be operated by a vacuum manifold including a receiving tray 44 and seal 15.


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It would have been obvious to use the columns of Horn with a receiving plate, gasket and manifold in order to provide a known alternative vacuum receiver as taught by Franciskovich. It would have been obvious to use different column packings to perform different separations as taught by Franciskovich. It would have been obvious to provide the claimed buffers in order to provide known buffers for the use of the columns as chromatography columns as taught by Horn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml
January 14, 2005